UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,799	08/29/2003	Patricia B. Hoyer	241331US20	7462

22850 7590 03/15/2006

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,799	HOYER	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-13,20-22,24-30,37-48,58,59, drawn to a non-transgenic non-human female having a characteristic of menopause induced by administration of VCD or VCH and methods of making, classified in class 514, subclass 9.2.

II. Claims 2-14,15,17,18,20-22,24-30,31 and 32, drawn to a transgenic knockout non-human female having a characteristic of menopause induced by administration of VCD or VCH and methods of making, classified in class 800, subclasses 9 and class 514, subclass 9.2.

III. Claims 2-14,16,17,19-22,24-30 and 31, drawn to a transgenic knockin non-human female having a characteristic of menopause induced by administration of VCD or VCH and methods of making, classified in class 800, subclass 9 and class 514, subclass 9.2.

IV. Claims 33-36 and 60, drawn to a method of screening an agent using a model of menopause, classified in class 514, subclass 9.2.

V. Claims 49-57, drawn to a solid composition comprising 4-vinylcyclohexene diepoxide, 4-vinylcyclohexene, 4-vinylcyclohexene-1,2-epoxide or 4-vinylcyclohexene-7,8-epoxide classified in class 585, subclass 20.

Group I contains claims relating to mutually exclusive species. For example claim 1 is drawn to the species 4-vinylcyclohexene diepoxide and 4-vinylcyclohexene. Claim 58 is drawn to the species 4-vinylcyclohexene-1,2-epoxide, 4-vinylcyclohexene-7,8-epoxide. Other generic

claims are drawn to all four species. Group I is subject to a species election as set forth below. Upon election of a single species, only the claims reading on that species will be examined with the elected group. If a species relating to claim 1 is elected, claim 58 will not be examined, and vice versa.

Claims 1 and 23 link(s) inventions I-III. The restriction requirement to the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 23. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are patentably distinct. The methods and product are drawn to genetically distinct animals that require different technical considerations in making and have different uses. Invention I is drawn to a non-transgenic animal whereas Inventions II and III are drawn to transgenic animals. Inventions II and III are distinct from one another because they comprise distinct types of genetic lesions that require different technical considerations in making and result in different phenotypes with different uses with respect top the disease modeled by the instant inventions. The transgenic animals can be used for genetic analysis of genes involved in the menopause process while the non-transgenic animals of Invention I can be used to induce ovarian failure as a means of population control or as a means for screening treatments. The inventions are classified differently. It would require an undue burden to search any of Inventions I-III together.

Inventions I-III and Invention IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case The animal models of Inventions I-III could be used to study menopause processes. Furthermore, many different, patentably distinct animals could be used in the method including different mutants that affect menopause in different ways.

Invention V and Inventions I-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product. See MPEP § 806.05(h). In the instant case menopause can be induced in other ways and the compounds can be used to make flame retardant materials.

Inventions IV and V are patentably distinct. Invention IV is drawn to a method of screening agents using a model of menopause that can be induced using different compounds and methods. Invention V is drawn to a substance that can induce menopause, among many other uses. The compound is not needed for the methods and the methods are not needed for the compound. The inventions are classified differently. It would require an undue burden to search Inventions IV and V together.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species restriction

1) This application contains claims directed to the following patentably distinct species: 1) 4-vinylcyclohexene diepoxide, 2) 4-vinylcyclohexene diepoxide, 3) 4-vinylcyclohexene-1,2-epoxide or 4) 4-vinylcyclohexene-7,8-epoxide. The species are independent or distinct because the compounds are structurally distinct compounds that are obvious one over the other.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 37,41,45 49 and 52 are generic to all four species. Claim 1 is generic to species 1 and 2. Claim 58 is generic to species 3 and 4. Upon election of a single species, only the claims reading on that species will be examined with the elected group.

2) This application contains claims directed to the following patentably distinct species: hot flashes, osteoporosis, incontinence, poylcystic ovarian disease, Alzheimer's disease, depression, macular degeneration, arthritis, anxiety, obesity, ovarian cancer, diabetes mellitus, vaginal dryness, vaginal discharge, cancers of the reproductive tract, breast cancer, thinning of the skin, loss of libido, colorectal cancer, alopecia, hirsutism, cardiovascular disorders, loss of manual dexterity, osteopenia, cognitive impairments, dementia, heart attack, stroke, deep vein thrombosis, hypertension, hypotension, ischemia, pulmonary embolism, atherosclerosis, heart abnormality, hypercholesterolemia, hypertriglyceridemia, hmocholesterolemia, hypotriglyceridemia, vascular defects, vascular homeostasis, and sudden cardiac death. The species are independent or distinct because the disease are different with different causes and different agents for potential treatment.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 33-35 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

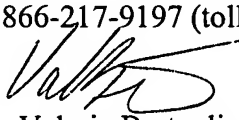
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Valarie Bertoglio
Examiner
Art Unit 1632